REMARKS

Applicants assume that the Examiner would pose the same rejection as posed in the 116 Amendment of March 10, 2008.

They commented upon many of the points made by the Examiner in the AMENDMENT...1.114(c) filed with the RCE of September 9, 2008, and the Examiner is requested to refer to that AMENDMENT...1.114(c).

In the present AMENDMENT, Applicants amend the current claims to limit the administration timing, the dose of the active ingredient, and demonstrate the significance of the administration timing within 10 minutes before starting meal by filing a DECLARATION UNDER 37 C.F.R. § 1.132.

Applicants respectfully submit that "within 10 minutes before starting meal" and "10 mg of miliglinide calcium salt hydrate" in the method of the present application is an administration timing and dose of the active ingredient which provides unexpected results which one of ordinary skill in the art would not be able to predict in any fashion. This administration timing permits the effects of the present method to be achieved. In fact, in Applicants' view, the administration timing and the dose of the active ingredient are key issues in the present method. None of the prior art discloses or suggests the administration timing and the dose of the active ingredient of the present application in any fashion. Thus, the prior art cannot anticipate the claims herein. Further, that subject matter of claim 14 is now included into claim 12; claim 14 was only rejected under 35 U.S.C. § 103(a). As a consequence, consideration of DECLARATION... evidence is appropriate.

Applicants respectfully submit that as presently claimed, the method of the present invention involves substantially different method steps (specific administration timing and dose of the active ingredient) from that disclosed in the prior art.

Applicants further submit that the effects of "lowering postprandial blood glucose levels and fasting blood glucose levels without causing prolonged hypoglycemia" are, in fact, results which would be unexpected to one of ordinary skill in the art. This is not simply a newly discovered inherent effect but is a result of the specific administration regimen, the specific amount and the specific materials used in accordance with the present invention.

Applicants would like to offer a few comments on the attached DECLARATION...1.132.

The attached DECLARATION...1.132 (hereafter simply the Declaration) is believed to be straight-forward and, rather than burden the record paraphrasing the Declaration, Applicants at this time offer only a few comments for the Examiner's consideration.

The purpose of the Declaration is to demonstrate the significance of the administration timing of within ten minutes before starting a meal by providing more detailed results then presented in the clinical study set forth in Example 4 on blood glucose levels and blood insulin levels before and after meal. The Declaration primarily goes to the results obtained regarding the effect of lowering postprandial blood glucose levels.

The beginning of the Declaration sets forth Declarant Kiyono's qualifications.

After discussing the Object of the study, the Test drug and Study design, the Declaration sets forth administration methods in Table 1. Of particular importance note Method 1 involves a placebo tablet, Method 4 involves administration 10 minutes before meal and Method 5 involves administration 30 minutes before meal. The measurement times for blood glucose levels and blood insulin levels are described in detail in the Declaration.

Blood glucose levels are given in Table 2. Declarant Kiyono, based on the results shown in Table 2, was able to reach the opinion 10 min before meal will cause less hypoglycemic symptoms than administration 30 min before meal (the Declaration, bottom of page 4). Further, in Method 5 (administered 30 min before meal), postprandial blood glucose did not decrease in comparison with Method 1 (placebo); see the Declaration top of page 5.

Declarant Kiyono was able, in conclusion, to state that administration at 30 sec, 5 min or 10 min before meal is better than administration at 30 min before meal because postprandial hyperglycemia was suppressed and a decrease in blood glucose levels before meal did not occur; see the Declaration at page 5.

Table 3 in the Declaration sets forth the results of blood insulin level testing. While Declarant Kiyono discusses the results in some detail in the Declaration at page 6, in the first full paragraph under Table 3 Declarant Kiyono concludes that insulin secretion before meal caused a decrease in blood glucose level before meal in Method 5 (administration 30 min before meal).

Importantly, in the paragraph bridging pages 6/7 of the Declaration, Declarant Kiyono is able to conclude that in the case of administration earlier than 10 min before meal, insulin secretion will occur earlier and that will increase the possibility of decreasing the blood glucose level before meal.

Declarant Kiyono's conclusions regarding unexpectedly superior results and the unexpected nature of the results are set forth in the first and second paragraphs at page 7 of the Declaration.

Considering the Declaration evidence and the state of the claims herein as now narrowed, withdrawal of all rejections and allowance is requested.